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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,903

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Stewart J. Lebrun

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10/27/2005

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,903

Applicant(s)

LEBRUN, STEWART J.

Examiner

Patricia A. Duffy

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 8-4-05 has been entered into the record. Claim 3 has been cancelled. Claims 1, 2, 4 and 5 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The previous rejections of record are withdrawn in view of Applicants amendments to the claims.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the

applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mroczkowski et al (US Patent No. 5,284,748, issued Feb 8, 1994; hereinafter Mroczkowski A) in view of Mroczkowski et al (US Patent No. 4,794,089, issued December 27, 1988; herein after Mroczkowski A), Harlow (Antibodies a Laboratory Manual, 1988, pages 563-566 and 579-582) and Herbrink et al (Journal of Immunological Methods, 48:293-298, 1982).

Mroczkowski A teaches a method for electrical detection of a binding reaction wherein the binding of two substances causes full or partial completion (closing) of an essentially open electrical circuit. The resulting change in the electrical state of the circuit indicates the binding reaction. The assay involves at least two electrical conductors (i.e. the instant electrodes) spaced apart on a substantially non-conductive base. The base has a support having a layer formed thereon, which has a high affinity for protein binding and moderate to high resistance in comparison to the conductors. The space between the conductors forms a path or channel. One of a pair of substances that bind each other is deposited or affixed to the binding layer of the non-conductive base between the conductors. Means forming an electrical circuit is connected to each of the conductors so that the channel or path constitutes a break in the circuit. The circuit is completed by binding of a second or third member labeled with a conductor. The assay is heterogeneous in that it comprises suitable washing steps (see column 5; columns 13-14). The assay is adaptable for the detection of either antigen or antibody (see columns 5-6). The assay is described as useful for determining specific amounts of specific antibody in a sample wherein a sandwich is formed of the complex of antigen-first antibody-second antibody conductive particle. The secondary antibody could be anti-IgG or anti-IgE. The resistance measurements of the circuit are inversely related to the amount of the first antibody in the sample (see column 7). Mroczkowski A teach that as an alternative to a

channel, diagnostic elements according to the invention, especially resistive shunting embodiments may utilize a resistive bioreactive path other than a channel. The reference differs by not teaching a spot, washing after every step and measuring current.

Mroczkowski B teaches a method for electrical detection of a binding reaction wherein essentially identical to Mroczkowski A, except that the presence of a member of a binding pair is measured by detection of the electrical current flow through the circuit formed by the electrically conductive particles upon binding to the first substance (see claim 1).

Harlow et al teach conventional indirect antibody capture assay and indirect antigen capture assay formats for the detection and quantitation of antibody and antigen respectively. Harlow et al teach the conventional wash steps after addition of the individual reagents in immunoassays (see pages 563-566 and pages 579-582).

Herbrink et al teach that immunoassays can be performed by using or applying a "spot" on a substrate.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify the method of Mroczkowski A by substituting the spot pattern of Herbrink et al for the channel, using the conventional techniques of the indirect antibody or antigen immunoassay methodology of Harlow et al and measure current as taught by Mroczkowski B because Mroczkowski A teaches that the assay is adaptable for the detection of either antigen or antibody (see columns 5-6), that as an alternatives to the channel may be used (i.e. bioreactive path other than a channel) and that the binding reaction can be detected electrically.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mroczkowski et al (US Patent No. 5,284,748, issued Feb 8, 1994; hereinafter Mroczkowski A), Mroczkowski et al (US Patent No. 4,794,089, issued December 27, 1988; herein after Mroczkowski A), Harlow (Antibodies a Laboratory Manual, 1988, pages 563-566 and 579-

582) and Herbrink et al (Journal of Immunological Methods, 48:293-298, 1982) as applied to claims 1 and 2 above, and further in view of Bartlett (US Patent No. 5,679,709, issued October 21, 1997).

The combination of Mroczkowski et al (US Patent No. 5,284,748, issued Feb 8, 1994; hereinafter Mroczkowski A) in view of Mroczkowski et al (US Patent No. 4,794,089, issued December 27, 1988; herein after Mroczkowski A), Harlow (Antibodies a Laboratory Manual, 1988, pages 563-566 and 579-582) and Herbrink et al (Journal of Immunological Methods, 48:293-298, 1982) is set forth supra. The combination differs by not detecting the autoimmune state of systemic lupus erythematosus (SLE) and IgG antibodies.

Bartlett et al teach that a feature of SLE is the presence of antibodies against nuclear constituents. The anti-ds DNA antibodies of the IgG class are SLE-specific and are used for diagnosis. Bartlett et al teach that the IgG anti-ds DNA antibodies are measured by conventional art methods using an ELISA.

It would have been prima facie obvious to one having ordinary skill in the art at the time that the invention was made to modify the assay as combined supra by substituting ds DNA as the antigen and detect anti-ds DNA antibodies in a sample for the diagnosis of the autoimmune disease SLE because Bartlett et al teach that anti- ds DNA antibodies of the IgG class are SLE-specific and Mroczkowski A teach that the assay is useful for determining specific amounts of specific antibody in a sample wherein a sandwich is formed of the complex of antigen-first antibody-second antibody conductive particle and the secondary antibody could be anti-IgG.

Claim Rejections - 35 USC § 112

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rendered indefinite from the use of an acronym that is not preceded by its full designation. While acronyms are permitted in the claims, there must be no ambiguity associated with their use.

Status of Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Pat A. Duffy
Patricia A. Duffy

Primary Examiner

Art Unit 1645